DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
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November 6, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Edward Iacino
President/Owner
Seattle Fish Company
6211 East 42nd Avenue
Denver, Colorado 80216

Ref. #: DEN-01-6

Dear Mr. Iacino:

On August 25 through 29, 2000, FDA Investigators Maryfrances Gardiner and Robert W. Becker, Jr., conducted an inspection of your seafood processing facility at the above address. The inspection revealed that seafood processed at your facility is adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). It is adulterated because it was processed and held under conditions contrary to the seafood processing regulations [Title 21, Code of Federal Regulations, Part 123 (21 CFR 123)], which constitute insanitary conditions whereby the food many have been rendered injurious to health.

The seafood processing regulations, which became effective December 18, 1997, require implementation of a preventative system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.

Our inspection revealed serious deviations from the seafood processing regulations that include, but are not limited to, the following:

Failure to develop and implement a written HACCP plan to control sulfites in shrimp repacked into tray packs as required under 21 CFR 123.6(b).

Failure to have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). Your firm's HACCP plan for histamine-producing species of fish and ready to eat seafood products lists a storage temperature monitoring frequency of (X) (X). This is not sufficient to ensure control of the food safety hazards of histamine-producing species of fish and ready to eat seafood products stored in the coolers or processing room.

For your information, the Office of Seafood considers vacuum packaged, raw or cooked ready to eat seafood to be a potential health hazard when refrigeration is the sole barrier to the growth of *Clostridium botulinum*. Refrigeration as the sole barrier would need to be continuously controlled and documented at 38°F or below. With current practices and abuses at the retail and consumer level, reliance on refrigeration to ensure safety is dangerous. Manufacturers must expect that at some point during storage, distribution, display or consumer handling of refrigerated foods, proper refrigeration temperatures will not be maintained.

Failure to implement the record keeping system listed in your HACCP plan for histamine-producing species of fish, to comply with 21 CFR 123.6(b). Your firm did not record monitoring observations for the shipping temperature critical control point listed in your HACCP plan for histamine-producing species of fish.

Failure to adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). Your firm did not monitor the condition of the water reservoir for the ice machine and did not assure that the faucets supplying water to cutting tables in the processing room had backflow prevention devices.

Failure to verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.8(a)(2)(ii). Your firm did not verify the accuracy of instruments and controls used for measuring and recording temperatures. Specifically, the two dial thermometers used daily to check internal temperatures of incoming histamine-producing species of fish revealed on 8/28/00, that one registered 25°F, the other registered 30°F in the same test conditions. Both thermometers were calibrated on 8/25/00. The frequency of calibration to assure the accuracy of the readouts should follow the thermometer manufacturer's recommendations. We are particularly concerned that these thermometers, which are used daily, give a 5°F difference within three days of calibration.

We acknowledge receipt of your letter, dated September 1, 2000. Your letter addresses specific corrections to your HACCP plan to control sulfites in shrimp repacked into tray packs and the observations involving the ice machine. However, your response did not include documentation or specific corrections regarding the other observations.

We may take further action if you do not promptly correct these violations. For instance, we may seize your product and or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

This letter in not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility as the President/Owner to ensure adherence to each requirement of the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110).

Please advise this office in writing within three (3) weeks from your receipt of this letter. Your response should outline the measures you have implemented to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations. Please direct your response to Mr. H. Thomas Warwick, Compliance Officer, at the above letterhead address or by telephone at 303-236-3054.

Sincerely,

Thomas A. Allison
District Director